Siemens LVO application Release Notes

Integration of StrokeSENS LVO 1.4 to Siemens Syngo.via

version 1.4.3 (LVO Build 59)

April 2023

CIRCLE NEUROVASCULAR IMAGING

Intended Use

StrokeSENS is a decision-aid software package to be used by clinicians to perform image processing, analysis, viewing and communication of computed tomography (CT) scans of the brain in patients with suspected acute stroke. Data and images are acquired through DICOM-compliant imaging devices prior to processing and analysis in StrokeSENS.

The StrokeSENS software provides analysis capabilities for imaging datasets acquired with standard CT imaging and contrast enhanced CT Angiography (CTA) modalities. Analysis of non-contrast CT images includes assessment of regions with suspected acute ischemic tissue. Analysis of contrast-enhanced CT images includes automated detection of anterior circulation Large Vessel Occlusion (LVO).

In the case of a suspected anterior circulation LVO, the system will send a notification to a pre-configured destination(s) (members of the acute stroke team), notifying them of the existence of a suspected LVO that requires review. The notification system is intended to be used in parallel to the standard of care workflow to notify clinicians of the existence of the case earlier than they may have been notified as part of the standard of care workflow. Images are available for viewing on a mobile device and on a standard radiology workstation. Images that are previewed on a mobile device are for informational purposes only and are not intended for diagnostic use beyond notification.

Device Description

Components of the finished integrated medical device include:

- The StrokeSENS LVO Processing Engine
- A Compatible Radiological Software Platform (Syngo.via)

The StrokeSENS LVO Processing Engine is a software-only device designed for operation with a compatible radiological software platform. The platform will:

1. Provide the CTA images used as input to the Processing Engine

2. Receive as output the indication whether an LVO was detected by the Processing Engine

3. Provide the necessary technological components for presenting the LVO notification to the clinician user (ie. email and user interface update)

The Compatible Radiological Software Platform (Siemens Syngo.via) is responsible for providing the CT image inputs. Based on the type of incoming DICOM data, the Processing Engine(s) is responsible to determine if the data is valid and suitable for processing and analysis.

Known Issues

Issue key	Summary
N/A	No known issues at time of release.

In the Build Package

- StrokeSENSLVO.exe
- LVO.dll
- MLC.dll

External Libraries – Copyright and Licensing Requirements

Library name	version	Licensing agreement	Download link
Tensorflow	1.13.2	Apache License 2.0	https://www.tensorflow.org/
Qt	5.9.3, 5.15.3	https://www.qt.io/terms-conditions/	https://login.qt.io/login
Eigen	3.3.7	Mozilla Public License, version 2.0	https://bitbucket.org/eigen/eigen/get/3.3.7.zip
DCMTK	3.6.7.1	http://dicom.offis.de/dcmjp2k.php.en	http://dicom.offis.de/dcmtk.php.en
OpenSSL	1.0.2u	https://www.openssl.org/source/license.txt	https://www.ooenssl.ora/source/
SimpleITK	2.0.2	https://github.com/SimpleITK/SimpleITK/blob/master/LICENSE	https://github.com/SimpleITK/SimpleITK/releases/tag/v2.0.2
Dcm2niix	1.0.20171215	https://github.com/rordenlab/dcm2niix/blob/master/license.txt	https://github.com/rordenlab/dcm2niix
GDCM	3.0.21	https://gdcm.sourceforge.net/Copyright.html	https://gdcm.sourceforge.net/wiki/index.php/Downloads

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